

Accelerating Therapeutic Innovation in Switzerland

The Therapeutic Products Act (TPA) entered into force two years ago with the objectives of accelerating market approvals and patient access to innovative products. What has been the experience since the revision date, specifically in the context of Covid-19 ?

The 13th ExEx symposium focuses on the TPA key aspects towards innovation and the meaning of global synergies, including the interaction of Swissmedic with international Health Authorities.

SwAPP events lay great emphasis on practical and lively discussions to favor exchange of ideas and experience between all participants, as well as the development of your career.

13:00 Welcome - *Frank van den Ouweland, President, SwAPP (Bern, CH)*

13:10 Onboarding Session

The revised TPA: a more flexible framework for innovative therapeutic products in Switzerland?

Rosa Stebler - Deputy Head Regulatory Operations & Development, Swissmedic (Bern, CH)

Corinne Wenger - Head of Drug Regulatory Affairs, Roche (Basel, CH)

Moderator: Doris Penna - Regulatory Affairs Manager, Eli Lilly (Geneva, CH)

13:50 Focus Session I

Tissue-agnostic therapy: innovation in oncology

Vanya Loroach - CEO, Loroach CTLS (Essertines-sur- Rolle, CH)

Gabriel Schnetzler - Project Team Leader Oncology, Roche Innovation Center, F. Hoffmann- La Roche (Basel, CH)

Moderator: Marc Schmid, Member of the Board, SwAPP (Bern, CH)

14:30 Focus Session II

Safety signals management

Renate Essen - Head Risk Management, Swissmedic (Bern, CH)

Alexandra Giger-Friedli - Pharmacovigilance Country Head (PVCH), Bayer (Schweiz) AG (Zurich, CH)

Moderator: Karin Vermot-Gaud Fornier - Sr Drug Safety Officer, Affiliate Resp. Pharmacovigilance Person (RPV), Eli Lilly (Geneva, CH)

15:10 Coffee break

15:30 Focus Session III

Developing therapies in emergency situation

Vanessa Kermer, Head Regulatory Affairs Switzerland, Pfizer AG (Zurich, CH)

Rosa Poetes, Partner, Leader of Pharma Regulatory practice in Europe, McKinsey & Company (Zurich, CH)

Moderator: Marc Schmid, Member of the Board, SwAPP (Bern, CH)

16:10 Outlook Session

Building up trust in international regulations: the need for synergy and collaboration

Andreas Pfenniger - Head Stakeholder Engagement, Swissmedic (Bern, CH)

Gabriela Zenhäusern - Deputy Head Stakeholder Engagement, Swissmedic (Bern, CH)

Rebecca Wood - Former Chief Counsel FDA; Partner & Co-Lead, Food Drug & Regulatory Practice, Sidley Austin LLP (Washington D.C., US)

Moderator: Doris Penna - Regulatory Affairs Manager, Eli Lilly (Geneva, CH)

16:40 Concluding remarks



16:45 - 17:30

e-Networking Apero



Registration

- Please register via “Xing Events” (you do not have to subscribe to Xing); see [here](#)
- Registration and payment are required prior to the symposium.
- To facilitate the organisation, please indicate on the registration platform if you join the e-networking cocktail.

Participation fees

SwAPP members	CHF 80.-
Non-members	CHF 300.-
New members (combi)*	CHF 250.- (up to Apr, 13 th)
Students (basic studies)	CHF 20.-

* Special offer including the registration at the present ExEx symposium and the SwAPP membership. Save CHF 50.- and as a SwAPP member, benefit from other discounts at further events of other entities !

Venue

On-line. Dial- in information will be send one day before the event.

SwAPP events term of conditions

By registering for this event you agree to SwAPP’s term of conditions regarding cancellation policy, photographs/videos/streams and lists of participants (please see [here](#)).

SwAPP is monitoring the Covid-19 situation carefully and focus on the safety of its audience. In case the present event would be easily feasible on-site, we will inform you and do our best to make it possible.

Accreditation

This event is accredited with 3.5 credits by SwAPP/SGPM and with 25 FPH credits for Hospital Pharmacy and Clinical Pharmacy by GSASA.

Learning Objectives

- To familiarize with key aspects of the Swiss TPA towards innovation, and in the context of globalization
- To understand the meaning of risk management in pharmacovigilance
- To become acquainted with the tissue-agnostic drug development approach
- To have an insight into the process of new therapies development in pandemic situation

Target Audience

New comers and experienced professionals interested in the development of therapeutic products, regulatory affairs, clinical affairs, quality, medical affairs, market access, process development; working in the Industry, Contract Research Organisations, Competent authorities, Notified bodies, Ethics Committees or Academia.

Friends of SwAPP

The ExEx Symposium is not sponsored. SwAPP benefits only from the support of other associations who publish the event on their communication platform without financial compensation.

